Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	Empacadora Del Golfo De México, S.A. De C.V	Site code	1089173
Site name	Empacadora Del Golfo De México, S.A. De C.V		
Scope of audit	Canning of fruits, sauces, and vegetables, acidified, thermally processed and non-thermal processed products: Whole jalapeño peppers, long sliced, nacho sliced jalapeño peppers, seedless jalapeño halves, chopped jalapeño peppers, diced jalapeño peppers, jalapeño puree. Whole green tomatillo, crushed green tomatillo, mild banana pepper rings, hot banana pepper rings, chipotle peppers in adobe sauce, chipotle peppers sauce, chipotle peppers paste, green and red Mexican sauce, packed in tin cans, plastic drums and pails, pouches, and pet jars.		
Exclusions from scope	Vinegar and ketchup sauce		
Justification for exclusion	Products are not done in a daily basis (just one time in a year), and direction do not require to be included in the certification.		
Audit start date	2024-02-12	Audit finish date	2024-02-15
Re-audit due date	2025-02-26	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose a module	Choose an item		
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit programme	Announced
Previous audit grade	AA+		Previous audit date	2022-11-22	
Certificate issue date	2024-04-10		Certificate expiry date	2025-04-09	
Number of non-conformities			Fundamental	0	
			Critical	0	

2. Audit Results

	Major	0
	Minor	2

3. Company Details

Site address	Av. Framboyanes No. 1393, Cd. Industrial Bruno Pagliai, Veracruz, 91697, Veracruz		
Country	México	Site telephone number	+52 229981 0614
Commercial representative name	Domingo de las Rivas	Email	domingo@faro.com.mx
Technical representative name	Esther Huerta	Email	aseguramiento@faro.com.mx

4. Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	501-1500	No. of HACCP plans	4-6

Shift pattern	3 shifts	
Seasonal site	No	
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.
Other certificates held	Kosher	
Outsourced processes	No	
Outsourced process description	None	
Regions exported to	North America Europe Asia Oceania South America Choose a region	
Company registration number	10490143368	

4. Company Profile

Major changes since last BRCGS audit	New quality manager, New areas, installation of new lines of production, new cleaning method.

Company Description

Empacadora del Golfo de México S.A. de C.V is a company coming from Mexican origin, located in Veracruz, Mexican private corporation dedicated to the canned and sauces sector in México, specialized. in the production, process and commercialization of canned vegetables and fruits.
The factory has 3 principles brands: Faro and La Comadre. Other trades: Great value, Savor imports, Nuestro campo.

- FDA: 10490143368
- DUNS NUMBER: 81062575
- FCE registration number 15315
- 526 employees.
- 3 shifts.

Manufacturing lines:

- Line: 105/160
- Line Hybrid
- Line 215
- Line 380
- Line 610
- Linea medium
- Line Packaging (Lemba 1 and Lemba 2)
- PET
- Barrells.

Relevant information regarding the audit's scope:

- Crops season: all the year, Peak season: July-September and February-April.
- Production volume: 15000 box/day (canned food), 3000 drums/year, pouch 850,000 boxes/year, PET 70,000 boxes/years.
- Number of retorts: 12 (vertical retorts) and 4 (continuous retort).
- Packaging presentation: canned food and vegetables with and without thermal process.
- Finished product presentation: pouches, plastic drums, plastic jars, and plastic buckets.
- Principal markets: foreign market (60%: Europe, North America, Oceania, Asia] and local market (approx. 40%).

It was finished 2 hours more due to 2 hours of review of Costco requirements.

Scope just was corrected spelling mistakes.

5. Product Characteristics

Product categories	06 - Prepared fruit, vegetables and nuts 11 - Low/high acid in cans/glass Category
Finished product safety rationale	Products were ambient stable, Minor pH 4.2, and thermal processing.

High care	No	High risk	No	Ambient high care	No

5. Product Characteristics	
Justification for area	Is low risk due the product is thermally acidified into their composition; the package protects the product after the filling machine.
Allergens handled on site	None Choose an allergen
Product claims made e.g. IP, organic	Kosher
Product recalls in last 12 months	No
Products in production at the time of the audit	Chile Nachos 310, 2.8kg., bags Chiles, chipotles.

6. Audit Duration Details			
Total audit duration	30 man hours	Duration of production facility inspection	15 man hours
Reasons for deviation from typical or expected audit duration	No deviation		
Combined audits	None		
Next audit type selected	Announced		

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)

Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Javier Pérez	Plant Director	Onsite		Onsite	onsite
Jose Antonio Saenz	Project manager	Onsite		onsite	onsite
Alejandra Espinoza	Shopping coordinator	Onsite	Onsite	onsite	onsite
Ramón Sanchez Rocha	Receipt Manager	Onsite	Onsite	onsite	Onsite
Rodrigo Saenz	Purchasing manager	Onsite	Onsite	onsite	onsite
Ivonne Orozco Martinez	Sanity supervisor		Onsite	onsite	onsite

Aida Vargas	Human resources manager	Onsite	Onsite	onsite	
Enrique Rivera	Maintenance manager	Onsite	Onsite	onsite	onsite
Daniel Martinez	Safety and Hygiene	Onsite	Onsite	onsite	onsite
Omar López	Production manager	Onsite	Onsite	onsite	onsite
Adriana Cruzado	Food Safety Coordinator	Onsite	Onsite	onsite	onsite
Esther Huerta	Quality Manager	Onsite	Onsite	onsite	onsite

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
2021-02-25	BRCGS food v 8.0	Announced	Pass
2022-02-04	BRCGS food v 8.0	Announced	Pass
2022-11-22	BRCGS food v 8.0	Unannounced	Pass

Document control			
CB Report number	MX/MEX/20110437		
Template name	F908 Food Safety Audit Report Template		
Standard issue	9	*Template issue date*	2022-12-16
Directory allocation	Food	*Version*	1.1

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
2.6.1	HACCP diagram observed not updated, application of chemical on chipotle raw material was not included. Although controls were reviewed without deviations.	The identification of the K-Biol product for the treatment of chipotle is included in the Selection and Blowing flowchart in the storage stage.	The HACCP team will take an advanced HACCP course to reinforce technical knowledge	When the flow chart was updated, the identification of the chemical application was not included; this was not done previously, but when the stock of dry chipotle increased, it was implemented as a preventive measure.	2024-03-04	Jorge Noguez
4.6.1	During site inspection it was observed tables in process area do not meet specifications stablished in data sheet (smooth and without a break).	It begins with a correction plan to replace all the stainless-steel sheets on the tables that are broken	As a preventive measure, the inspection of the physical condition of the tables is implemented through a GMP checklist, on a monthly basis.	In the risk analysis, it was detected that the deterioration of the tables is caused by wear during production.	2024-03-04	Jorge Noguez

Comments on non-conformities
Click or tap here to enter text.

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Lead auditor		
Auditor number	**First name**	**Second name**
25783	Jorge	Noguez

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Jorge	Noguez	25783	Lead auditor	2024/02/12	08:30	17:30	Physical	
Jorge	Noguez	25783	Lead auditor	2024/02/13	08:30	17:30	Physical	
Jorge	Noguez	25783	Lead auditor	2024/02/14	08:30	17:30	Physical	
Jorge	Noguez	25783	Lead auditor	2024/02/15	08:30	14:30	Physical	
Elvira	Guzmán	NA	Technical Expert	2024/02/12	08:30	17:30	Remote	

1. Senior management commitment

Policy was observed posted in the facility (entrance of the facility); it was reviewed that was documented in "JP" Date: August 2022. Confirmed that policy fulfils the BRCGS requirements: quality, food safety, legal and authentic; as also with the food/quality culture. It was confirmed that policy is communicated through It is published in each room, in training, email, Culture Plan. During audit it was interviewed some staff and answered correctly about it.

During audit it was interviewed "JP", and it was confirmed that facility had an Improvement plan/culture plan and activities documented in Culture plan documented in Culture Plan

- They reviewed objectives of the indicators
- 5S, equipment conditions and prerequisites
- Staff knowledge assessments
- Bulletins of deviations from process situations (negligence)

It was confirmed that the level of culture is measured with KPI. It was confirmed that it was planned to be reviewed annually, last review of the plan of culture February 2023.

Activities:

- Newsletters
- Videos
- 15-minute talks on quality, safety, legality and authenticity
- Implementation of daily checklist.

For effectiveness it was confirmed that plan was monitored through the following KPIS of the facility, they are monitored monthly in monthly meetings.

Site senior management stablished the following objectives, they were reviewed, and no deviation observed:

- Non-conforming product. Target 0.5%. Result of 0.4%.
- Customer complaints (number of complaints per 1000 boxes received). 2.3, objective 1.
- Second part audits comply
- Complaints from clients, authorities or internally for food fraud
- No complaints
- Fines or Recall: no recall 2023.
- Culture: compression of the talks. Objective 80%, result 82.4.
- Target quality bulletins 15%, result 15%.

During audit it was interviewed staff, and they have awareness regarding the complaints followed during the last year.

During audit, it was interviewed General manager "JP", and was confirmed that facility performed management review according to the 1.1.4 requirements of the standard, it was documented, it was done (January 24th, 2024). Some of the topics reviewed on document "Minutes of meeting for review by management":

- Internal audit findings.
- Internal audit.
- Food defense and food fraud: no deviation.
- Client internal audit / last BRCGS audit: 3 findings.
- KPIs
- HACCP.
- Recall
- Culture plan.

Improvements: They acquired equipment for the tomato-based product line, preparation tank, CIP equipment, filler, and sealer. Surveillance cameras. Purchase of a Comitrol and a washing machine for line 215.

Follow up actions are agreed in the management review, and they are reviewed during the next management review. Since they established to perform 12 management review during a year, follow up actions can perfectly be done.

It was confirmed that facility performed monthly meeting, where they discussed Quality, Food safety.

- Evidence reviewed: January 12th, 2024. / Result of audits, PRP, corrective actions, complaints, and food defense.

The way the staff of the facility reports hazards or infractions anonymously and confidentially is through the confidentiality Physical mailbox or electronic mailbox, which included food safety, quality, authenticity, and legal issues in the catering area. In case of existing a concern, they fill the record. There were no reports during the last year and considered in the Food safety culture.

- Mailbox for complaints:
- Complaint systems.

It was reviewed the current personnel resources and facility resources during the site inspection, they were observed adequate: company provides enough staff team ad resources.

For keeping updated, Facility has many ways they keep always been updated Verification of legal compliance, Food fraud and Marking withdrawal. Sample taken:

- Pesticides
- Market recall
- Federal Code of Regulations.
- Water.

It was confirmed the site has the copy of standard Issue 9 as PDF copy version and printed version.

It was confirmed that due date of the audit was stablished in certificate MX10/80471 on February 26th, 2024, so this audit was done on time.

The most senior management staff of the site FM attended the opening meeting and closing meeting and discussed culture plan. Relevant staff were available during audit.

During the interview with General Manager FM, it was confirmed that NC from the last audit were followed up (11 minor non-conformities from last recertification audit). Root Cause analysis follow up actions are reviewed with no deviation.

It was confirmed that BRCGS logo is used according to the requirements of BRCGS and used only in the web page.

It was confirmed that Site had registration with authorities, example taken from local government license of municipal operating of Mexican government.

It was reviewed the current personnel resources and facility resources during the site tour, the company provide the personnel team ad resources as defined in the company Organization Chart. Structure reviewed:

- Organization chart: Organization chart: RH-ORG-GRAL / General Director, Production Director, Maintenance Manager, Project Manager, Purchasing Manager, Programmer, Warehouse Manager, Commercial Director Human Resources Manager, Administrative Manager.
- Backup are described in job descriptions. Food Safety Coordinator/Chief Safety Officer.

There is a key personnel matrix at the platform. Succession plans. This plant is for the absence plan for the key staff in the job descriptions.

- Job position: General Worker. Education required: Elementary school. Evidence: certificate reviewed of staff without deviation.
- Job position: Quality specialist and/or raw materials and materials management specialist from another shift. Education required: Engineer. Evidence reviewed: Certificate reviewed of staff without deviation.

During site inspection it was interviewed staff, and they answered with awareness regarding their responsibilities and demonstrate that they work according to their policies and procedures.

During site inspection it was interviewed staff regarding report of unsafe or out of specification process/products and they answered correctly. Some answers include:

- Any unsafe product must be reported to Quality /supervisors
- Report them on the food safety inbox

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.2.4	No external expertise used

2. The Food Safety Plan – HACCP

It was conducted the site tour for the site inspection from receiving, shipping, production. It was confirmed the defined team for HACCP program, reviewed the team competent and the documentation for the current HACCP program. It was confirmed that HACCP team is multidisciplinary, documented, it was documented in AC-APPCC-1.

- EHG / Head of Quality Assurance (Food Safety Team Leader)
- ACH / Safety Coordinator
- OLO / Production Manager
- DDG / Head of maintenance
- JAS / Project Manager
- RSR / Warehouse Manager
- RSTF / Purchasing Manager

Training done by the HACCP alliance training course. Date from November 11 to 13, 2020. It is carried out with the supplier “CA”.

It was confirmed that the scope of the HACCP analysis included the products/ and processes done on of the facility: Canning of fruits, sauces, and vegetables, acidified, thermally processed and non thermal processed products: Whole jalapeño peppers, long sliced, nacho sliced jalapeño peppers, seedless jalapeño halves, chopped jalapeño peppers, diced jalapeño peppers, jalapeño puree.

Whole green tomatillo crushed green tomatillo, mild banana pepper rings, hot banana pepper rings, chipotle peppers in adobe sauce, chipotle peppers sauce, chipotle peppers paste, green and red Mexican sauce, packed in tin cans, plastic drums and pails, pouches, and pet jars.

Exclusion: Vinegar and ketchup sauce

It was confirmed that Facility stablished prerequisites as required in 2.2.1, evidence reviewed during the Audit report of BRCGS. Verification of prerequisites is done during internal audit and self-inspections based on risk. Evidence reviewed in 3.4.4.

Facility only had many finished products within the scope.

- Canned: AC-AAPPCC-1. Reception of raw material (chili peppers, tomatillo), Manual selection, Rinsing and destoning, Cutting, Line pumping.
- Slicing: Magneto, Blow, Rinse and stone, cut, Optical selection, Pump to line.
- Pickling: Reception of raw materials (Carrot and onion), Blanching, Peeling, rinsing, Cutting, packaging, adding brine, Storage, emptying.
- Brines and Sauces: Reception of ingredients, storage, formulation of the covering liquid, heating, shipping to line.
- Canning: Rinsing and destoning, blanching or hydrating, packaging and weighing, addition of coating liquid, pre-sterilization, Crimping, Can washing, Commercial sterilization, Drying, Labeling, coding and boxing, Storage and shipping.
- Sauces: AC-HACCP-4: AAPPCC-2: Processes without thermal process (PET bags and jars). Formulation of the covering liquid.
- Solid-liquid packaging, Metal detection.
- Industrial products.

Flow diagram was confirmed during site inspection. It was confirmed that verification of the flow chart was conducted on December 12th, 2023, by the HACCP team.

Sample taken of a specification of finished product Chipotle Pepper in adobo sauce (last update was confirmed done in December 2023):

- AC-ESP-PT-48. Product: Chipotle Pepper in adobo sauce. 24/7. Raw Materials: Ingredients: Chipotle pepper, water, Tomato paste, salt, sugar, onion and Acetic acid. Sensory characteristics: appearance, odor, flavor, texture, color. Chemical characteristic: % acidity 1.2 to 9.2. pH 3.9 max, % salt 3 to 1. Microbiology: Aerobic mesophiles negative, anaerobic mesophiles, mold and yeast negative. Chemicals: Lead, Cadmium, arsenic, less than 1 mg/kg. Tin less than 100 mg/kg. Pesticides: according to the matrix of the country to be sold. Packaging: Tinplate 211/209x300. Shelf life 1095 days. 3 years.
- Nachos Sliced Jalapeño Peppers AC-ESP-PT-50. Raw Materials: Ingredients: Jalapeño pepper, water, salt and Acetic Acid. Sensory characteristics: appearance, odor, flavor, texture, color. Chemical characteristic: % acidity .9 to 0.2. pH 3.8 max, % salt 3 to 1. Packaging: Tinplate 211/209x300. Life of shelf. 3 years. Pouches: 1 year. Drums and drums. 1 year. Pet jars: 2 years. Intended use: Food service, no vulnerable groups except for metabisulphite. Thermal: canned.Non-thermal: bag, petjar, pails, drums.

Raw Materials Specification

- Onion: ACP-ESP-MAT-CEB. Appearance whole, healthy, fresh, free of peel, free of decomposition, firm and smooth consistency, white and yellow color, characteristic odor. Pesticides within the maximum limits, heavy metals, small, medium and large parameters.
- Salt: ACP-ESP-ING-SGR. Heavy metals, arsenic, cadmium, copper, mercury, lead. Irradiated, pH, Purity 97.5%, insoluble, magnesium, sulfate ion.
- Petjar: transparent PET plastic jar, manufactured with high virgin purity, transparent color, Complies with 21 CFR 177.1630,

It was confirmed that verification of the flow chart was carried out on November 30th, 2023, by the HACCP team.

Methodology

Facility identified in their HACCP analysis based on Codex Alimentarius the following methodology:
Severity:

- Critical: requires medical intervention
- Major: sometimes requires medical attention
- Minor: rarely needs medical attention
- Undetectable: no effect.

Probability

- Frequent: continually occurring
- Likely: will occur frequently
- Occasional: will happen sometimes
- Remote: Rarely, but expected
- Unlikely: rarely but possible.

Significant hazards. Multiplication of greater than or equal to 12. PCC are determined with a Codex Alimentarius decision tree.

Evidence reviewed:

- Physical: Foreign matter contamination, plastic gloves. Probability: Unlikely, Severity, Minor. Score: 2. Not significant. Controls: Good glove practices staff training, GMP inspection of gloves.
- Biological: Increase in bacteria: Salmonella, Listeria Monocytogenes, clostridium botulinum, B. cereus. Improbable Probability, Severity, Catastrophic. Score of 5. Not significant. Controls: cleaning and sanitization procedures, cleaning verification procedures, process controls (acidification and sterilization).
- Allergenic. Contamination with allergens due to bad practices. Probability: Unlikely, Severity catastrophic. Score of 5. Not significant. Controls: Staff training, staff GMP, Inspection of process areas.
- Chemical. Contamination of products due to the addition of uncleared additives (sulfites). Probability: Unlikely, Severity Catastrophic. Score 5. Controls: Sulfites in a specific area, exclusive tanks, Training.
- Radiologic: Water. Control NOM127 analysis.
- Food defense and Food fraud are analyzed in deferential analysis.

CPP

Canned 2 CPPs:

1- Closing system. Critical limit. It depends on the format of the can. Example: 202x200x204x0.0302" minimum. Monitoring: The overlap is reviewed at the beginning of the process, every 90 minutes of the process, changes in container foate, supplier or caliber, or machine adjustment. With a mathematical formula. Responsible mechanic for crimping. Verification: With closure projector equipment or micrometer measurement once per shift by specialists or analysts from the quality and safety area. Corrective actions: Inform quality. Validate the result with 3 cans from each head involved if the deviation is repeated in 2 of them, stop the line and make an adjustment. Quality will validate 3 cans with the projector equipment. If the adjustment has been made, the process cannot continue until the deviation is corrected. Separate the product since the last effective revision.

2- Commercial sterilization (Retort/Autoclave): Critical limit: Format 2.8 kg 5 min 98°C minimum. Monitoring. At the beginning of the process and every 15 minutes (temperature), time (at the beginning of the process. By the continuous cooker. Verification. Review of the temperature indicator and recording. 1 time per shift by analysts from the quality and safety area. Corrective actions: Stop the equipment or adjust it using a steam control valve as appropriate, inform the

quality and safety area, identify the quantity of product and segregate it as NCP. Identify the quantity of affected product and segregate it as NCP.

Without thermal process.

- Formulation: Critical brine limits pH 3 max. Monitoring The pH of each batch of brine is monitored prior to being used in the process. Monitors the quality and safety analyst specialist. Verification of the pH of the finished product at 24 hours by production and safety specialists. ACMP-AN-pH. Corrective actions: Recirculate the brine in the tank for an additional 30 minutes, repeat analysis if the deformulation adjustment occurs again, brine cannot be released until it meets the critical limit.
- Solid-liquid ratio. Correlation of drained mass and volume of covering liquid. Critical limit. 1.31 max. Monitoring by quality personnel. Every 60 minutes. Check. pH of finished product according to AC-MP-AN-pH. Corrective actions: If the relationship is wrong, the process is stopped, the product is resampled, the adjustment is made, the product produced since the last effective review is segregated, samples of the batch are taken, according to the results obtained, the product can be released. or reprocess during the product.
- Metal detection: Critical limit of correct operation (band stopped, light activation). Ferrous 2.5 mm, Non-ferrous 3.5 mm, Stainless 5 mm. Responsible for the bagging production line manager. Corrective actions. The process is stopped, the product is segregated, the sensitivity and rejection parameters of the recipes are reviewed, once the equipment adequately detects the witnesses since the last immediate or scheduled successful review. Verification: Detection test by specialists, quality and safety analysts once per shift.

Industrialized (Diced dehydrobrine)

- Salt, acetic acid and jalapeño are added. Critical limit for each 113 kg preparation add 3.4 L of acetic acid, 15.8 L of salt. Puree according to a formulation table. Monitoring: carried out by a production manager with the weighing of ingredients on a calibrated scale. Corrective actions stop the process, inform the supervisor, adjust parameters, segregate the finished product from the last review as PNC for subsequent review. Verification: By the quality specialist or analyst, the pH of the samples is checked according to AC-MP-AN-PH.

Validation

- CPP 1.- Closing Systems. August 23, 2023. Bibliographic information, historical data. STANDARD 130 and Canadian Food Inspection Agency.
- CPP 2. Commercial sterilization. Historical analysis of temperature / time results, results of aerobic mesophilic results, anaerobic mesophilic results. NOM 130.
- CPP3.- May 5, 2023 / PH. References and historical data.
- CPP 4. Solid-liquid relationship. July 8th, 2023. Technical references, results,
- CPP 5. November 3rd. Results of historical data and trends of customer complaints.
- CPP 6. May 5, 2023 / References and historical data.

Legal requirement reviewed: Validation of thermal authority.

- Continuous Cooker-Cooler:External supplier “SCIA”, / march 30th, 2023 / Nachos Jalapeño pepers in Brine (Acidified to pH 3.8). 80 °C , temperature esterilización 97°C, sterilizing 4.5 minitues. Continuous Cooker- cooler. (heating medium, water immersion). Critical factors: Fill weight 1.640 g maximum. Equilibrium pH at 24 hours menor de 3.8 maximum. Dimension jalapeño peper 3/8”. Hold time 30 miutes maximum. Product formulation and preparation producedures

- Non-continuous: Heat penetration study (July 14th, 2021). Chipotle Pepper in adobo sauce. Packaed in 209(211x300 3 pieces. Initial temperature 57°C. Processing temperature 110C. Procesing time 15 minutes. Minimum cooling time 20 minutes. Fill weight 8.3 oz. Whole chipotle pepper 8.3. Adobo sauce 5.8 oz. Acidity 1%. Can position vertical. Maximum hold time 90 time.

Confirmed that their last HACCP Verification. Frequency: annually. Last one done on November 17th, 2023.

During site inspection and in the vertical audit it was challenged devices and records and no deviation observed. Example of corrections / corrective actions resulted from the PPR were reviewed in 3.7 and 3.8.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	None

3. Food safety and quality management system

3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

This Manual is review at appropriate intervals or improvements. During site inspection it was challenged to production staff of the site, and it was verified that they can access to the folder.

During site inspection it was interviewed staff and those answered correctly to the importance of the procedures that they had done in the facility, and they were requested to show the procedures, with no deviation. It was confirmed that documents were available in Spanish (all staff talks Spanish) and clearly legible.

They stablished that document are available and stored in folders. Specification and form in the quality management system. It was reviewed:

- Management of the system: In case of new documents procedure AC-SGC-PCD. Approvals for new procedures: Leader responsible of the area.
- List of documents // It was confirmed that are controlled through the records procedure. For approval of documents is created by supervisor, approved by Documentary control.
- Reviewed the system 19 AC MP CP BD current documented information control list identified the current revision and the issue of the current revision of the controlled documents.
- During the audit procedures were reviewed with no deviations.
- Procedures control AC-SGC-PCD, confirmed that is established that one year one month. (shelf life plus 5 months). System backups are made frequently: it was challenged one electronic folder with IT department, and they showed a Screenshot from system showing that system was perfectly backup. Evidence reviewed:
- During traceability challenge to the facility, documents reviewed were observed legible, appropriately authorized, retained in good condition, and retriable. It was confirmed that the records reviewed alterations were not observed.

For records control confirmed that facility had the procedure “AC-SGC-CR,” it was reviewed that facility had the Records control procedure documented in platform. It was confirmed that:

- Master list of records: according to the platform, they showed the report where all records can be traceable and showing last version.
- Records were stored 4.5 years (1.5 time the shelf life plus).
- Every area is responsible for their records.

3.4 Internal audits

It was confirmed that internal audit procedure is documented in AC-SGC-PRAI. They stablished to perform then throughout the year, all the BRCGS requirements, with more emphasis on the requirements that more findings they had according to risk analysis AC-00C-PAI, conformed that frequency of audits has been determined based on risk and results of previous audit.

If was confirmed that they performed their 4 internal audits, per year. Confirmed that the last 5 internal audits were done according to program:

- Report October 27th, 2023 / AC-CC-AUD /2
- Report of August 14, 2023 / AC-CC-AUD /2
- Report of April 20th, 2023. /AC-CC-AUD /2
- Report of August 17th, 2023 / AC-CC-AUD /2
- Report of October 25th, 2023 / AC-CC-AUD /2

Records reviewed of reports confirmed identified conformity and non-conformity. Criteria Matrix for internal audit.

- CC and ER.

Confirmed that internal auditors were independent (they are from different areas) and received training:
- Training RH-CA-LA1 / Training of 19011 / Date: March 10th, 2023.
- Training BRCGS, December 20th. 2022.

Internal audit findings (major, minor and no findings). External audit findings, classification of areas, RNC for safety, RNC product service.

Evidence reviewed: Internal audit program 2023, CAR reviewed in 3.7.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

It was confirmed that facility had the Classification procedure AC-SGC-INS approval of suppliers of goods and services for raw material and packaging material suppliers based on risk assessment and quality as follows:
- High risk supplier: GFSI
- Medium risk supplier: GFSI or audit
- Low risk supplier: cuestionario

Confirmed that facility had their updated list / database of approved suppliers. During audit it was challenged some of them. Evidence reviewed:
- Onion supplier: Low risk
- PET JAR supplier: Low risk
- Salt supplier: Low risk
- Bag supplier: Low risk

Evidence requested during audit:
- PETJAR supplier: GFSI certificate (FSSC): / Date: September 2025.
- Bag supplier / FSSC (GFSI certificate). Date: November 24th, 2024.
- Salt supplier: questionario (Food safety coordinator). December 2023.
- Onion supplier: Date: March 24th, 2023. Questionnarire.

For assuring traceability facility requested certificates and traceability exercises. Records reviewed:
- Traceability: AC-BPM-PTRA-PROV. 30-10-2024. Lote CD. No deviation.

For evaluation facility stablished to perform an evaluation every year, as a result they evaluate according to this parameter:
- Document update Quality and Safety
- Service (requested term)
- Service (requested quantity)
- Price competitiveness
- End user evaluation.

Evidence reviewed:
- AC-SGC-EVA-PROV. Evaluation of suppliers: Onion supplier 92%, PET JAR supplier 90%, Bag supplier 95%, and Salt supplier 100%.

For emergency suppliers, they must be used the same procedure, but it must be done quicker. No emergency suppliers were used during the last year.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

It was confirmed that the organization has a Procedure Review entrance to the facilities, physical requirements, safety requirements Reception AI-MP-IT-01 raw material and packaging material sample procedure. Quality staff is responsible for the documentary review in each delivery of raw material and finished product Invoice, purchase order, quality certificate, seals are corroborated, fumigation certificate of the unit. During site inspection it was reviewed the following reception:

- Transportation inspection for receipt of materials / checklist ALIT/ 1 / Responsible “S”. Reviewed of Transport “T”. Date: February 12th, 2024.
- Chile batch 3275 C3. Chile reception: Date October 2, 2023 / Yurécuaro Michoacan / Reception: J. Transport: Transport revision "S". Date of October 2, 2023.

In case of a change, it was confirmed that HACCP leader must inform to production the changes related to them. No changes done during the last year. Raw materials and packaging materials are evaluated according to their matrix. Evidence reviewed in 5.6.

3.5.3 Management of suppliers of services

For services they stablished that they had the procedure approval and evaluation of services for supplier evaluation AC-SGC-INS approval of suppliers of goods and services for raw material and packaging material suppliers. For new service suppliers they identified specific requirements for suppliers.

- Evidence reviewed: Accreditation 17025.

It was confirmed that facility had the following service suppliers “Concentrated Service Providers” list. They stablished to monitor the following services: Pest control, cleaning, chemicals, and lab. Sample taken from the evaluations:

- Calibration 100%
- Pest management 100%

Criteria:

- Quality and Safety
- Service (requested term)
- Service (requested quantity)
- Price competitiveness
- End user evaluation.

Records reviewed of their evaluations, confirmed that suppliers do not require corrective actions. It was confirmed that service suppliers had an agreement (contract) where they stipulated the services they had. During audit it was challenged the site with the contracts of the transport and the Pest management supplier.

- Transport supplier: evidence reviewed in 4.16.6
- Contract Pest management: evidence reviewed in 4.14

3.5.4 Management of Outsourced processing

Not outsourced processing

3.6 Specifications

The facility has defined and available the specifications (raw, intermediate, and finished product) to ensure compliance with product safety and legal requirements. It was confirmed the specification of finished product and evaluated according to vertical audit in traceability. Specifications of raw materials followed during audit:

- AC-ESP-PT-48. Product: Chipotle Pepper in adobo sauce. 24/7. Raw Materials: Ingredients: Chipotle pepper, water, Tomato paste, salt, sugar, onion and Acetic acid. Sensory characteristics: appearance, odor, flavor, texture, color. Chemical characteristic: % acidity 1.2 to 9.2. pH 3.9 max, % salt 3 to 1. Microbiology: Aerobic mesophiles negative, anaerobic mesophiles, mold and yeast negative. Chemicals: Lead, Cadmium, arsenic, less than 1 mg/kg. Tin less than 100 mg/kg. Pesticides: according to the matrix of the country to be sold. Packaging: Tinplate 211/209x300. Shelf life 1095 days. 3 years.
- Nachos Sliced Jalapeño Peppers AC-ESP-PT-50. Raw Materials: Ingredients: Jalapeño pepper, water, salt and Acetic Acid. Sensory characteristics: appearance, odor, flavor, texture, color. Chemical characteristic: % acidity .9 to 0.2. pH 3.8 max, % salt 3 to 1. Packaging: Tinplate 211/209x300. Life of shelf. 3 years. Pouches: 1 year. Drums and drums. 1 year. Pet jars: 2 years. Intended use: Food service, no vulnerable groups except for metabisulphite. Thermal: canned. Non-thermal: bag, petjar, pails, drums.

Reviewed that they had agreement for the manufacturing customer-branded products that handle on the site. Reviewed from client “W”, January 2023. No deviation observed.

Raw Materials Specification

- Onion: ACP-ESP-MAT-CEB. Appearance whole, healthy, fresh, free of peel, free of decomposition, firm and smooth consistency, white and yellow color, characteristic odor. Pesticides within the maximum limits, heavy metals, small, medium and large parameters.
- Salt: ACP-ESP-ING-SGR. Heavy metals, arsenic, cadmium, copper, mercury, lead. Irradiated, pH, Purity 97.5%, insoluble, magnesium, sulfate ion.
- Petjar: transparent PET plastic jar, manufactured with high virgin purity, transparent color, Complies with 21 CFR 177.1630,

Confirmed that facility had a procedure of review of specifications. It is done annually even they don’t have any changes. Confirmed that they performed that review in 2023.

3.7 Corrective and preventive actions

It was confirmed that facility for corrective actions had the corrective and preventive action procedure AC-SGC-PAC/P. It was confirmed that they must raise a non-conformity in the following cases:

- First party audit findings
- Non-compliance with GMP
- Preventive or improvement actions
- Second part findings
- Nonconforming product
- Customer complaints
- Incidents that may affect safety, quality, or legality
- Regulatory non-compliance.

It stablished that in case of non-conforming product they do:

- Summary of corrective actions for 2022 / 2023 / 2024 /. Trigger, / Root Cause Analysis, Finding, Responsible.

When asked available reports used for internal, they manage all the corrective actions, they are managed through a database.

During audit it was followed the corrective actions of the 8 minors finding of the last internal audit.

- Root cause analysis ACP / 1-CP. The customer found a 0.5 inch wooden stem. Corrective actions: a complaint will be made to the supplier for parameters out of coincidence. Containment measures are executed involving production personnel to control the process and ensure that the product meets the specification. Date of 07-19-2023.

3.8 Control of non-conforming product

It was confirmed that for handling non-conforming product, facility had the non-compliant product procedure AC-SGC-PNC. It stablished that in case of non-conforming product they

- Quality detects that a certain product does not meet the established specifications.
- If product arrives out of specification, it meets with the food safety team.
- Assurance detects that the product does not comply with the formulation and enters the non-conforming product procedures.

Non-conforming product complies that it does not comply with the specification (damage catalogue). A retention card is placed with the information on the non-compliant products. The area manager is notified, it is retained in the System, it is segregated in a defined area, it was determined whether it is corrected or reclassified. The corresponding supervisor is informed and recorded. It was observed an Improvement trend. Confirmed that authority for releasing non-conform product is the quality department. During site inspection confirmed that in warehouse there is a place for non-conform product.

3.9 Traceability

It was confirmed that Facility for traceability of all the raw materials that are used in the facility, they used records according to the procedure Traceability procedure AC-BPMPTRA-01 where they stablished those 2 drills are stipulated in a period of 1 year, it must be 2 hours.

During traceability challenge it was reviewed that facility can easily identify all the raw materials from a selected random date and identify which supplier and batch number is affected. During site inspection it was reviewed that facility had controls, so Traceability is not lost during production. Rework is not done in the facility, they stablished that they only could do modifications of deviation in process and managed as non-conform product.

Finished products can be traceable according to a number that is assigned to each box. During audit it was reviewed that controls are followed, and traceability is not lost. It was confirmed that site performed a traceability during the last year. During audit it was challenged the facility with the following traceability:

Traceability:
Procedure: AC-BPM-PTRA-01 / Traceability matrix.
3 drills (ingredients)

finished product (1 exercise)
Recall (1 exercise).

Documents:
Traceability checklist: ACTZ / 1-a.
Product: Jalapeno slices 3.78L. Batch. 3275 Quantity 1214 pieces (20 pallets). / 1 container.

Jalapeno pepper:
PET line closure record / PREL/10-01 / Line start

Chile batch 3275 C3.
Chile reception: Date October 2, 2023 / Yurécuaro Michoacan / Reception: J
Transport: Transport revision "S". Date of October 2, 2023.
Laboratory: Inspection certificate: "VM". Reception October 2, 2023.
Critical defects: rotten, rotten, fungus, yellow, dehydrated, seed.
PGR-MP-01 Certificate / Date of October 2, 2023.

Salt
Daily preparation and consumption report for the brine room and kitchen / PRCO/1.
salt batch 3266 is used /
Base 3271. Roche. "Y"/
Salina Roche Commercial Certificate. /

PET
Lot 3258
Reception date.
Supplier "I". / Certificate September 13th, 2023.
Inspection by "S". Date of 09-15-2023.

Top
3208
Cover reception

CPP
Formulation: ACLC / 1. "B". No deviation
Solid-liquid relationship: Monitoring of control points and critical control points.

Net content: ACPC-CN / Oct /21. Verification of net content. (Check). Comply.
Monitoring of control products and critical control points /

Cleaning records
PRLI/21 / Date of October 2, 2023.
ACVL/01 / Date of 10-2-2023 /
PURL! /9-2 & oxiplus and foming plus

Release
ACPT/ 11.: 3-10-2023. Physicochemical parameters, quality defects, sensory characteristics, evaluation of primary packaging, coding, and labelling. Liberation. Release.

Process control and quality control key documentation reviewed documented in 5.5, 5.6, 5.7, 6.1, 6.2, 6.3.
Process records reviewed:

- CPP records
- Quality release records
- Labelling records

- Process variables records
- Legal weighting records reviewed

Reviewed they identified where was the destination of the product.

3.10 Complaint-handling

It was confirmed that complaints are managed according to the Procedure complaints managing procedure AC-SGC-GQJ. In case of a complaint confirmed that they do the following steps:

- Email is sent to the Management system manager. The following information is requested: complaint, arrival date, pallet, lot, photograph, condition, description.
- Clientes se quejan por el ventas, por desarrollo y con gerente de sistema de gestión .
- A complaint sheet is assigned. The report is reviewed, and the complaint is passed to documentary control.Times of response: 5 buisness days.

Confirmed that trends go to down during the last years:

- 2022: 45 complaints
- 2023: 29 complaints

Complaints:

- Damaged packaging (9)
- Out of specification (9)
- Labelling error (6)

Evidence reviewed: Reason for complaint: ACP/1-CP. The customer detected a cloth inside the product. The areas and use of the rags are not clearly defined. Personnel move through any area without any restrictions. Actions establish rag control by generating a list of rags in process lines.

3.11 Management of incidents, product withdrawal and product recall

It was confirmed that facility had an emergency procedure AC-SGC-INC Emergency care plan (Crisis management procedure.

- Emergencies identified: Fires, flood, earthquake, hurricane winds, explosion.
- Activities related to the product: Quality inspected the site for looking any kind of deviation.
- December 21st 2023. Fire drill. Quality reviews the site and there is no impact.

It was confirmed that facility in case of a Recall they had the Product withdrawal procedure VEN-MP-RC. They stablished that they must consider:

- Type 1: where the use or exposure to the product may have serious or fatal consequences for the consumer or may imply regulatory/legal non-compliance.
- Type 2: It is a situation where use or exposure can cause non-serious effects or fatality for the consumer.
- Confirmed that facility contemplates to advice SGS in case of a recall within 3 days, according to procedure VEN-MP-RC. Actions to do in case of Recall in less than 21 days:
    - Steps to follow: withdrawal alert, key personnel meeting, document review.Traceability, Mass balance, Customer is notified.

Last drill was done AC-BPM-PTRA-PEJ. Exercise / 12-11-2023 / Green sliced jalapeño pepper 6/10 tracked quantity 15098 pieces. less than 2 hours. Traceability of blue open drum / 178-7 / 300 pieces. No deviation. less than 2 hours.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
3.5.4	Not outsourced processing

4. Site standards

4.1 External standards

During audit it was reviewed in a layout and during site inspection that facility is an industrial area, the neighbours are not industrial facilities. Not evidence of pest, wasteland, adjacent watercourses at risk of flooding, or neighbouring companies with odour taint potential. Neighbours reviewed:

- South: Open field.
- North: Parcel storage warehouses
- East: Parcel storage warehouses
- West: Open field.

During site audit it was confirmed that facility had self-inspections documented in 3.4.4 where facility review external areas to ensure that no contamination can be done on the areas.
During site inspection it was reviewed the exterior of the facility and it was observed the local activities, there was observed that overgrown vegetation, risk of flooding and standing of water not observed. It was requested and confirmed that neighbours do not constitute a risk for quality/legality/safety of the product.
External areas were observed maintained in good order: no excess of waste or other debris, no pest or stagnant water observed. Building fabric observed maintained in good order, no risk of damage was identified.
No external storage observed. For site security it was observed:

- CCTV (number no revealed for facility security) and recordings with backup.
- External security supplier 24 hours (external supplier).
- Restrict access to facility

4.2 Site security and food defence

It was confirmed that facility undertook a documented risk assessment documented in Food defence AC-SGC-FDP, Date of last update January 30th, 2024. Followed the Methodology, Evaluation of the areas was conducted, according to:

- Exterior measurements
- Interior measurements
- Staff security measures
- Measures to respond to incidents.

During audit some of the Process stages were reviewed:
Methodology: KAT.

- Calculation of potential impact on public health
- Degree of physical access to the product
- Ability to consider a successful attacker
- Ability to consider an attacker.

Elaboration of premises. High threats.

- Examples of controls: Access control, chlorination control, Key records (only personnel on the list have access to keys), Surveillance cameras. Access, 24/7 Surveillance.
- Challenge was done on January 12th, 2024. Efective 100%. No deviation.
- Confirmed that FDA requirements were considered and no deviation observed.

It was confirmed that staff who participated in threats analysis took food defence training. This requirement is mandatory for FDA regulation. Evidence reviewed:

- February 2023, Attendance List.

4.3 Layout, product flow and segregation

During site inspection it was followed the current map of the facility, it was challenged, and it was observed updated, and observed that indicated how personnel access and travel between areas. It was confirmed that production process flow is continuous and there is not risk of potential mixing rising to non-compliant products.
It was confirmed during site inspection that equipment was located with sufficient space to allow easy access for operating cleaning and maintenance. It was confirmed that not rework is done in the facility, so direct handling of the product is not done. It was confirmed and reviewed on site that there is:

- Layout for the entry of Key personnel general plan
- Layout flow plan where they identified how staff flows were identified.
- Layout of water: Autocad layout observed.

Facility had external suppliers that work in plant (Cleaning, gardening, property, medical). Training external supplier: good practices, Order and cleanliness, good storage practices. Training date: January 2024.
Not temporary structures observed during site inspection. Not defined areas of high care/high-risk areas
4.3.6 Not temporary structures observed during site inspection

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

During site inspection it was noticed that there were the following areas: production area/warehouses. Administrative area: Dressing rooms, dining rooms, offices. It was confirmed that:

- Process area: 10/106 area, Hybrid area, 215 area, 380 area, 610 area, Medium area, Lamba 1 and Lamba 2 packaging area, PET area, Barrica area. Material: aluminium sheet, cement floor with gray paint. Yellow signage.
- Warehouses: aluminium sheet, cement floor with gray paint. Yellow signage.

Pipework was observed clean and in good state of repair, free from flaking paint. Ceiling was observed with good maintenance. Internal drainage does not open to operation areas, during site its inspection it was noticed that there were not unpleasant Odors were observed in site inspection. It was confirmed that all lights that are in process were observed protected and monitored. It was confirmed that UV Lamps are protected. During site inspection it was confirmed that lighting was adequate and can allow to staff to monitor quality and defects of the finished product. Ventilation was observed adequate, the production area is a big area. It was confirmed that not dust, fumes, condensation was observed. Doors of production area were observed in good conditions. In production area they do not have injection of air. Plastic strip curtains observed clean and with good condition in warehouses, in packaging area.

4.4.5 not suspended ceiling were observed during site inspection, 4.4.6 not elevated walkways were observed during site inspection, 4.4.7 not windows are used for ventilation observed during site inspection.

4.5 Utilities – water, ice, air and other gases

The organization has identified the following utilities for the process:

<u>Water</u>
Water: Confirmed that water was obtained from their own well. Treatment of water: chlorine addition. Documents reviewed:

- Flow Diagram: The water comes from a well, it is stored in a cistern, and chlorine treatment is carried out.
- Evidence of cleaning of the cistern. January 2023. And is planned to be done every two years.
- For potability they performed annually the following analysis according to Mexican law regulation NOM127 (it included microbiology, chemical, radiology). Analysis of NOM127: Analysis done by

external supplier DSU. Date: August 2nd, 2023. No deviation observed. Accreditation 17025 reviewed.
- Example of quarterly water monitoring. Date of November 27, 2023. / August 2023. Fecal coliforms, and E coli. No deviation.

Vapor is used for thermal process and is in contact with product. Evidence reviewed of maintenance.
- January 2023 Report / External supplier "GT".
- Evidence reviewed for culinary filters: Date: December 20th, 2023.
- Reviewed datasheet of culinary filter "D". food contact according to 21 CFR and EC/1935/2004.

Facility had 3 compressors for compressed air for pneumatic functions. Maintenance reviewed:
- Date: June 28th, 2023. External supplier: "I". Air filters, cleaning, retightening.
- Date: October 10th, 2023. External supplier "I". Air filters, cleaning, retightening.

4.6 Equipment

Facility did not have any new equipment, but it was stablished that specification of new equipment must be discussed with food safety team and according to Maintenance procedure must agree with sanitary design and easily cleaning. There is no Mexican law regarding this topic. Aspects to be considered:
- All direct food contact equipment must be sanitary in design, cleanable, capable of producing safe products, smooth surfaces, adequate seals, welds and joints..

During the site inspection, it was confirmed that equipment that has direct contact with food were designed and built to facilitate cleaning, disinfection, and maintenance.

Confirmed that facility had their risk-based commissioning procedure for new equipment AC-SGC-PES. During audit it was reviewed the actions taken after they received their new equipment:
- Evidence: Report of equipment supplier "SLM". Date May 4, 2023.

All mobile equipment (including mobile equipment used for cleaning, and forklift of warehouses) observed clean and cannot be considered a risk for product.

4.6.5 No unused equipment observed stored, and all equipment observed clean. 4.6.7 Not battery equipment in open product areas.

4.7 Maintenance

For preventive maintenance, facility had the staff Maintenance Analyst, with the use of a software. All Equipment and task were loaded in the system with stablished frequency. At the start of the month, all the activities were recalled, and assigned to the maintenance responsible (supervisors, and then by technicians, electricians, and mechanical staff. Once the activity is done, area responsible review that all the activities were done correctly and perform a release of the area observing that is clean and no risk to the product. Evidence reviewed:
- Confirmed MT-SGC-PRMT that at the end of the maintenance according to the procedure, they must inspect that there is not missing parts and that is clean. During audit, it was observed the start-up process of one of the mixing lines and all process was observed according to procedure.

Facility stablished those temporary repairs according to procedure MT-SGC-PRMT, must be done only in cases where they did not have the part available and did not pose a risk for quality/food safety.

During site inspection no temporary repairs observed. Evidence reviewed:
- Seamers, Positioned bands.
- Maintenance 3 compressors: They are made with the supplier "IR" Ingersoll Rand, Date December 2023.
- Internal closures // The preventive maintenance program 2023 MT-PRO-CERR is in place. There is a program between or two major interventions.

- Preventive maintenance of the seaming machine 40P, C2 202 S/R was reviewed. Responsible Gregorio Jacome and Nestor Isaac. Change of bushings, heads, transmissions, general cleaning are reviewed.
- Metal detectors (calibrations) // It is carried out with the supplier Calibration: Date of January 6th, 2024. External supplier "D". Accreditation PJLA 101514. Ferrous 2.5, Non-ferrous 3.5, and Stainless 5.
- Thermal process (calibration) / Comintec. Verification of temperature recorder is carried out. / /It is carried out on November, 2023
- Mt-CRO-LIN-24 / Program. Autoclave 1. Report. External provider “GP”. Cleaning, uncovering, enamel application.

During factory inspection observed maintenance workshop and observed where maintenance store their tools and obsolete equipment. It was observed clean and since it is in a separated area from production there is no risk for metal debris. Also observed proper storage of food grade lubricant.

4.8 Staff facilities

It was confirmed that facility had a changings facility one for women and one for men. In this area staff changes their clothes to uniform that is delivered by the facility. Cleaning of the uniform is done by an internal laundry on the facility even they do not use protective cloths and all areas is product closed (no risk). It was confirmed that the size of this area was observed adequate.

Storage of the personal items are done in lockers that are in the changing facilities. During site inspection no evidence of mobile phones, or other objects in process areas. It was evidence that outdoor clothing is not stored with work clothing.

At entrance, there is a hand-washing facilities:

- Customs handwashing: handwashing technique signs. Soap, Sanitizer. Appropriate instruction for use in Spanish, water in sufficient quantity and a suitable temperature (not reflex of quitting the hands observed), hands free operation, liquid soap, and paper for drying hands.

Facility had two bathrooms (one for men and other for women), that were observed out of the production area, it was confirmed that they do not open directly into production (there is a ventilated space between toilet and production area). It was confirmed that smoking is not allowed in the facility and no evidence of smoking in production areas were observed. Food it was confirmed that is only stored in catering room (that is far from production area). During site inspection it was challenged all the desks and cubicles inside production area, and no food or chewing gum observed. Allergens coming from the catering facilities observed controlled, they are only stored in a room that is separated from production area. It was confirmed that there’s not high care / high risk areas identified during site inspection.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

For chemical control facility identified the procedure Chemical products handling. Non-food chemicals were observed stored and managed correctly. During audit it was observed the following controls:

- Safety data sheet reviewed of chemicals with no deviations.
- Data Sheet Master List Consumption log in Maintenance / December 2023.

During site inspection it was confirmed that all chemicals were identified

- Training of use of chemicals were reviewed, was done. Evidence reviewed: Training of GMP of Maintenance / February 8th, 2024 / ER.
- Warehouse for the chemicals products was observed locked, with only access to authorized personnel
- It was interviewed staff during site inspection and they know the correct handle of them.

- Reviewed procedure manage any spillage documented in GMP procedure Manual of Good Manufacturing Practices Personnel, described that any spillage must be segregated and properly cleaned. Chemical waste is managed according to 4.12.
- No scented or taint-forming materials are used in the facility.

4.9.2 Metal control

It was confirmed that facility had the Metal Policy foreign material program metal policy AC-BPM-PV: handle knives and blades for cutting raw materials. Date: November 27th, 2023, in which they stablished that snap-off blades are not used in the facility. They used controlled knives inspected. During site inspection it was confirmed that they followed their policy, and that staples, paper clips or similar metallic items are not used.

Confirmed that they used knives, and for better control they had the record Metals inventory, and they stablished to do an inspection every shift.

4.9.3 Glass, brittle plastic, ceramics and similar materials

It was confirmed that facility had the Procedure AC-BPM-PV Handling glass, plastics, brittles, and ceramics. Scope: utensils, laboratory material, porters, platforms, security equipment attachment, forklifts, personal glasses, external personnel. They identified the following controls:

- Map: Brittle glass map is available, frequency every two months. Record reviewed:
- Glass and britlle material control // Plastic inventory
- Rigid plastics: daily
  - Rigid plastic, production: quarterly
  - Metall: direct contact sharpening: daily
  - Glass, lenses semi-annual production
  - Glass: windows, Forklift mirror, quarterly
- Glass break procedure: In case of breakage of a glass, the area is abandoned, the non-conforming product is identified, the person responsible, the utensils, notifies quality. The report is filled out. No breakages during the last year.
- Glass observed in Solely area: lamp, light cover, multivac screen, refrigerator doors.
- Production windows observed protected, UV lamps from the flying insects were observed protected and no risk for production contamination observed
- Training: Material breakage policy / Date: November 23. Training AC.

4.9.4 Products packed into glass or other brittle containers

4.9.4 NA: Not glass or brittle containers.

4.9.5 Wood

It was confirmed that facility had the wood policy and practice in Wood policy procedure where stablished that wood is only used for pallets according to PR-MAD-01. The only wood that is allowed is the pallet. The guideline is available. It has a magnet and basket type filter. During site inspection it was observed that equipment and desks are not made of wood and pallets were in good conditions. No wood observed in open product areas. Facility identified some areas where they identified that pallets can be damaged and had dedicated spaces for collocating the remaining wood that can be broken.

4.9.6 Other physical contaminants

During site inspection it was interviewed production staff who were the responsible for opening the raw material and it was answered that prior to the opening of raw materials. Confirmed that:

- Pens are only allowed near inspection area for records filling, it was confirmed that it was controlled, and no issues identified.
- Mobile phones / tablets / similar portable items are not allowed, confirmed that it was controlled, and no issues identified.

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

It was confirmed that facility considered in the HACCP analysis that foreign body in the finished product the facility. It was confirmed that facility considered in the HACCP analysis that foreign body in the finished product the facility. Facility identified as CPP Metal detector.
Reviewed during site inspection also reviewed that facility had inspection tables for the review of chili. Observed that operators separate and reviewed the raw material (chili), no deviation observed.

4.10.2 Filters and sieves

It was confirmed that filters are used in brine production area, diameter 1.5 and 2 mm, and confirmed that they are inspected every time they are used: At start and end of production. No deviation observed.

4.10.3 Metal detectors and X-ray equipment

It was confirmed that facility considered in the HACCP analysis that foreign body in the finished product the facility. Facility identified as CPP Metal detector:

- Metal detection: Critical limit of correct operation (band stopped, light activation). Ferrous 2.5 mm, Non-ferrous 3.5 mm, Stainless 5 mm. Responsible for the bagging production line manager. Corrective actions. The process is stopped, the product is segregated, the sensitivity and rejection parameters of the recipes are reviewed, once the equipment adequately detects the witnesses since the last immediate or scheduled successful review. Verification: Detection test by specialists, quality and safety analysts once per shift.

During site inspection it was challenged metal detector, and confirmed that critical limits non-Fe 3.5, Fe 2.5, and SS 55 mm, were followed. Record RE445-4 filled correctly. During site inspection it was confirmed that metal detector had system rejection in place and worked properly. Product rejected observed properly segregated, no risk for reincorporation to release.

4.10.4 Magnets

For magnets controls, there was followed the Inventory stablished by facility MT-ZON-PLA-MA. They identified the location, line, type, brand, measurements, scope are reviewed. It has been defined that the criterion is 30% of their capacity. Verification reviewed:

- Magnets: Date of. January 6, 2024 / Magnetic plate. 1567 Gaus / 1800 GAUS minimum 70%.

4.10.5 Optical sorting equipment

4.10.5 N/A Not optical sorting equipment was used in the facility

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

Facility used mainly Cans for packaging. They are elaborated from an external supplier, and they are only feed to the packaging area. All cans are new, and they are not required to be cleaned.

4.10.7 Other foreign-body detection and removal equipment

4.10.7 No other foreign body detection / removal equipment used in facility.

4.11 Housekeeping and hygiene

During site inspection it was noticed that there were the following areas: production area/warehouses. Administrative area: Dressing rooms, dining rooms, offices. It was confirmed that:

- Process area: 10/106 area, Hybrid area, 215 area, 380 area, 610 area, Medium area, Lamba 1 and Lamba 2 packaging area, PET area, Barrica area. Material: aluminium sheet, cement floor with gray paint. Yellow signage.
- Warehouses: aluminium sheet, cement floor with gray paint. Yellow signage

Other areas: restrooms, lockers room, catering area (food storage), nursery room, maintenance room

Process areas were observed clean and with no risk to the product.

During audit, the third day it was observed the cleaning of the production area. It was followed up the cleaning instructions, which were documented in Procedures, where it was confirmed that they detailed the equipment, frequency, responsibilities, materials and equipment, preparation of the area, preparation of the solution, cleaning and sanitizing procedure, monitoring, verification and validation, acceptance, actions corrective. Evidence reviewed:

- Cleaning procedure AC-PSA-PG-08.
- Tank cleaning / January 2024 / External supplier. No deviation observed.

Chemicals reviewed during site inspection:

- Foaming plus 1100 -22000 ppm / Supplier “N”. / Reviewed that was Food grade and used according specification.
- Sanitizante Oxxi plus 80 a 35000 ppm. / Reviewed that was Food grade and used according specification.

During audit it was followed the cleaning of one of the tanks of the day of the audit. For effectiveness they performed visual inspection. Records reviewed:

- AC-PSA-VSL-16 cleaning assessment procedure
- Chemical verification / PRL1/42-1.

During audit it was challenged facility with the training records for cleaning and chemicals, no deviation observed. Facility for cleaning they used fibre that did not had the potential to shed fibres. Equipment’s were observed that located in a production room that is hygienically designed for cleaning after use.

- Training: IT, competence matrix, procedure, chemical management, Date of 03-13-2023. / Training by health supervisor “IO”.

For cleaning effectiveness, facility performed the following activities:

- Verification at the end
- Visual: all cleanings
- ATP: Monthly verification. They stablished the Specification: 0-150 URL release line. 151 to 300 URL perform flush, greater than 300 URL URL validation.

Records reviewed:

- ACV/ 01 / Cleaning Validation Form / Date of 02-08-2024.

Trends of microbiological monitoring analysis were reviewed in 4.11.8. In case of trends deviation, they stablished to perform another cleaning. During hygiene verification during audit, it was interviewed responsible for cleaning: sanity supervisor, and Production staff, who answered correctly of how to clean, chemicals dosages, verification system, and they are aware from the environmental microbiological monitoring. During audit it was witnessed one cleaning process in the mixing area, observed done correctly.

4.11.7 Cleaning in place (CIP)

4.11.7 NA. No CIPS on facility

4.11.8 Environmental monitoring

It was confirmed that facility had a program based on risk assessment documented in environmental monitoring program AC-BPM-PANA Ambiental monitoring. A risk analysis was conducted: they determined that they are a low-risk area. They stablished that:

- Indicators: Total coliforms, Total coliforms, E coli, aerobic mesophiles.
- Areas: Elevators, Pumping pipes, Uniforms.
- Analysis is performed by an external provide “M”.
- Frequency of analysis: Every 3 months.
- Limit: It has been established according to NOM093, there is a total count of less than 100 UF, coliforms less than 50UFC.
- Trends: 2023.

Facility stablished control limits according to legal requirements. In case of deviations, they specified corrective actions. Last review of the program was done during the last year in January 2024.

4.12 Waste and waste disposal

Waste is retired at the end of each shift, according to the layout. Waste is collocated in wastebaskets and bags that are covered. No issues observed. Procedure SS-MA-PRR-02. It was confirmed that according to Waste collection procedure non-hazardous waste procedure available on platform. An external supplier manages waste “G.” Licenses and contract were reviewed; they were approved by government.

It was confirmed that in the facility, waste storage is collected in waste collection containers which were observed identified, well maintained, covered and without signs of pest consumption. It was confirmed that external supplier destroys the trademarks. Evidence reviewed of waste is under control:

- Manifesto f7-01-2023 / External supplier “G”. Lamps and contaminated solids.
- Chilli manifesto / External supplier “P”. Food waste chili waste / December 2023.
- Waste cans / External supplier “RC” / Can waste and chitarra are discarded / Date of July 2023.
- Dining room waste / External supplier ID” Date of February 12, 2024.

4.13 Management of surplus food and products for animal feed

4.13 No surplus or animal feed destiny for waste.

4.14 Pest management

It was confirmed that the pest management according to the procedure POP-RTK-0018 is done by an external supplier “MCP”. Legal approval: 2007-30A-142. Undetermined time license. It was confirmed that contract was signed January 2024 and valid until next year. Contract reviewed, signed on January 2024, and confirmed it was still valid. It was reviewed the calendar of activities documented in Service Calendar, where they stablished the following:

Service:

- 14 light traps
- 55 rubber traps
- 25 rubber balancing traps
- 104 priming stations
- Fly control bucket

Extraordinary chemical application,

Reports reviewed.

- Report of February 10, 2023 / 14 light traps / Technician: GZ /
- November 2023 Report / Technician CCM.

Facility performed a Risk assessment analysis documented in “AR-RTK-01920868, 2023. During audit it was challenged devices and it was reviewed reports of October 2023 of the facility:

Chemical application followed during audit:

- Chemical DelKop / Dose 20 ml/l / Used according to the recommendation of the
- Legal requirement RSCO-URB-INAC-119-384-008-03.

It was confirmed that trends of 2023 were stable.

It was confirmed that all devices were identified in the layout: Layout: May 2023. It was confirmed that facility stablished the frequency of services according to a risk assessment as follows (four visit per month) documented in MIP in 2023. Risk assessment evaluation methodology. Date: December 2023.

Training reviewed of technician:

- Integrated Pest Management / Date: June 5th, 2020. / CONOCER certificate.

The company implemented measures to prevent the access of pest into the facility, devices are collocated in and out the facility to capture pest. Good storage practices were observed, and no external space is used for storage. It was confirmed that all waste were not stored in the facility. In case of the waste, they are managed through external supplier.

To prevent birds, enter to building and roosting, observed the construction (example wall with ceiling properly sealed) as well into the pest control management system include birds control plan.

During site inspection it was interviewed staff and they answered that in case of pest finding they must notify to quality staff or production supervisor. No deviation observed.

Last in-depth inspection was reviewed AR-RTK-01920868, December 2023. Confirmed to be done annually (based on a documented risk assessment), and plan reviewed from findings resulted from the plan.

4.15 Storage facilities

It was confirmed that in facility they had the following warehouses for storage: one for raw materials, one for labelling, and one for finished products. It was confirmed that facility had the documented storage procedures:

- storage good practices, AL-MP-RP-01
- procedure for order and cleaning, AL-PT-LP-01
- FIFO for finished product procedure, AL-MP-SP-03.
- Loading policy, AL-MP-SP-03.

They stablished that this area is closed and restricted. It was confirmed that facility didn't manage any kind of allergens (they manage sensitives and it they were observed controlled in a restricted area). It was confirmed that facility didn't store anything in the outside part of the facility. Cans packaging of the products are stored separately and protected with plastic bags. It was confirmed that all finished products and raw materials were identified with their batch number, so they can be easily traceable. Temperature storage conditions was confirmed that is not required for the quality / food safety / legality of the product. Controlled atmosphere was confirmed that is not required for the quality/food safety / legality of the product. It was confirmed that facility to ensure stock rotation, the facility has put in place the FIFO procedure (First in First Out). During site inspection of the warehouses, it was confirmed that they didn't have any out of expire raw materials / finished products.

4.16 Dispatch and transport

It was confirmed that facility for transport finished product they used third party contractors. Evidence reviewed:

- List of transport providers: they had the following suppliers: "JAS". mainly.

Confirmed that they had contracts with the BRCGS requirements of 4.16. Evidence reviewed:

- Contract signed by supplier "JAS". / January 2nd, 2024.

According to the procedure AL-MP-IT-03, it was confirmed that facility performed a review of the transport and performed a checklist Finished product loading. During site inspection, where the vehicle was inspected for cleaning, good conditions, no temperature required. It was challenged the record of the product:

- ACIT // December 2023. Inspection of transport done by Quality staff, with no deviation
- ACIT/ June 2023 was revised. Reviewed: Roof, canvas, looks, doors, tires were reviewed.

A delivery of product, it was interviewed staff responsible for the transport verification and answered correctly for the loading and unloading practices. It was confirmed that areas of loading properly designed for loading activities, no sign of pest/birds on site.
During Audit it was interviewed Logistics responsible, and it commented that they had procedures for reviewing the conditions for product and transport in case of failure and breakdown of transport (Procedure AL-MP-IT-03 Logistics and shipping). No incidents during the last year, just complete theft of the transport.

4.16.3. Not temperature on transport.
4.16.4 Not internal transport is used in the facility, only external.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.4.5	not suspended ceiling were observed during site inspection
4.4.6	not elevated walkways were observed during site inspection
4.4.7	not windows are used for ventilation observed during site inspection
4.6.5	No unused equipment observed stored, and all equipment observed clean.
4.6.7	Not battery equipment in open product areas.
4.9.4	Not glass or brittle containers.
4.10.2	No filters / sieves
4.10.4	No magnets on process.
4.10.6	No container cleanliness.
4.10.7	No other foreign body detection / removal equipment used in facility
4.11.7	No CIP in place
4.13	No surplus or animal feed destiny for waste.
4.15.4	no controlled atmosphere is required
4.15.5	no outside storage is done in facility
4.16.3.	Not temperature on transport.

4.16.4	Not internal transport is used in the facility, only external.

5. Product control

5.1 Product design/development

Facility stablished the Research and development procedure new product development AC-CC-PRY/01 where they stablished the steps to follow in case of a new product is done in the facility.

- Management establishes the Project
- Development and research performs the tests
- HACCP is evaluated

During the audit, the PR-FM-ME/56-22 chipotle sauce protocol is observed (it has already passed the laboratory stage). Steps followed:

- Element of change, documentary evaluation of materials and safety, change control specialist.
- Evaluation at the laboratory level, industrial test execution, laboratory test execution, validation of the change.
- Approach of the packaging material, packaging or ingredient, develop or redesign.
- Request for documentary information and sample, review of documentation and testing at the laboratory level.
- Request for samples for industrial testing, coordination of the test, testing at the industrial level, verification and validation of the product, evaluation of results and defining acceptability or rejection, validation of the change during 3 productions after the approval of the change.
- Tests of 4 pallets: 230 to 233F, 15 minutes. Net content 215g, filling t, closing t 80°C Can washer t 70 80°C.
- Shelf Life // Established 3 years.

No new product reviewed during last year. During last year it was produces product Chipotle sauce 24/2015. / A penetration check was performed. Reviewed by Food safety Manager / Date June 2023

Shelf life: Confirmed that they have studies stablished according to the previous products.

- 3 years to the canning
- 1: bags, buckets, barrels,
- 2: PET, jalapeño.

In case those products are different an external supplier. Evidence reviewed:

Validation and Verification of shelflife: 1) Aptitude test on August 29th, 2023 / They consider variables: acidity. 2) Checklist for shelf life studies AC /vda/01 Date of 09-21-2023. Adobo chipotles. No deviations.

5.2 Product labelling

It was confirmed that the facility sold products in many countries. They stablished the Labelling procedure. available on electronic platform. The final product is a generic product that is not intended use for the final consumer.

- Records reviewed ACAA/1 Sept 22, arts approval.

Reviewed during site that the staff responsible for creating the label is “Capture process.” During site inspection was observed that controls were corrected.

The product is transport in boxes, not required nutritional claims or specific legal requirements for the customers however labelling is in line with legal and industrial requirements. The label used is approved by the quality department.

It was confirmed that proper controls were observed for labels that responsibility is from client: they can be traced, and in case of change they can be perfectly modified in finished product. Confirmed that no claims are used on products (only Kosher) Evidence reviewed:

- Labell reviewed: ACAA/1/ Sept 22. Labell Best Choice Store / Requirements, Quality, Safety, Nutritional information, Legality, Mechanical plan.
- Changes on the labels / are done on ACCC/April 1, Label arts change control
- Certificate of conformity NO221822UCCNOM-051-SCFI/ SSA1-2010000119.

Reviewed database “theoretical calculations of nutritional information”, where they have the theoretical nutrimental calculations of the finished products.

5.2.3 NA. No label responsibilities from clients since all products are from site.
5.2.4 NA. Not cooking instructions

5.3 Management of allergens

It was confirmed that facility performed a raw material assessment documented in HACCP analysis, where they stablished that there’s not allergen on site. Confirmed that there’s not allergen managed on site. It was confirmed that according to the AC-PM-PCA Allergen Procedure and Allergen prevention. Allergen prevention the food is segregated in catering area, and before entering they must wash their hands. Layout of flow of the people were observed and matched during site inspection and no deviation observed. It was confirmed that finished product did not have any allergen claims. Evidence reviewed:

- It was confirmed and challenged site, and it was confirmed that there’s no food in production areas.
- Raw materials used for the product: chili, salt, vinegar, etc. No allergens on site.
- Controls: development and research identifies raw materials, in storage there are defined places and it is identified with a label, Analysis with health release of allergen KIT, brushes and dedicated utensils, there are only soft drink vending machines.
- It was confirmed on site inspection that there was not allergen.
- Lubricants technical data Allergen free declaration observed.
- Training and awareness done by employees: GMP and Allergen training: November 2023

5.4 Product authenticity, claims and chain of custody

As detailed in 1.1.8 information relating to the adulteration or substitution or raw materials was confirmed that facility had up-to-date knowledge of relevant scientific publication, monthly committees, FDA. Facility mitigation activities were included in the vulnerability assessment. It was confirmed that facility had a Vulnerability risk, substitution, or Fraud Assessment documented AC-SGC-EVFR.

- Premiu lab.
- Supply chain
- Audit strategy
- Relationship with supplier
- History of regulatory quality or supplier safety problems,
- Susceptibility of quality specification methods
- geopolitical considerations,
- Fraud history
- Economic anomaly.
- Impact on health: focused consumption
- Nutritional Sufficiency
- Economic impact

- Public trust.

Example of controls: Laboratory analysis, guarantee letters, Approved supplier system.

Last annual verification of Food fraud vulnerability analysis: February 5th, 2024.

Confirmed that staff had training of food fraud. Evidence reviewed:
- Training: July 2023. / Internal Training / December 10th 2021. Trainer “PH”

Reviewed Best choice Salsa de chipotle 215 g. Date November 30th, 2023. / Review of label with no deviation

5.4.5 Confirmed that there are no claims managed by the facility.
5.4.6 Confirmed that there are no claims managed by the facility.
5.4.7 Confirmed that there are no claims managed by the facility.

5.5 Product packaging

Finished product used as primary packaging the following materials: Label, mesh. It was reviewed the specification of finished product and confirmed that is suitable for the kind of products that are produced on site. Evidence reviewed:
- compliance letters indicating that meets FDA regulations; there was certificate of analyses to demonstrate compliance to relevant food safety regulations mentioned in this letter and certificate of analyses.
- IEMCO gallon is used. Date of February 11, 2022. The resins used by the supplier comply with 21 CFR 177.1630.
- Cans are produced in a facility certified in BRCGS standard (Certificate reviewed with no deviation).

During site inspection it was reviewed that packaging materials are separately stored in warehouse and protected in bags. Not observed risk of cross contamination.
- PET. Lot 3258. Receipt of date. Supplier "I". / Certificate September 13rd, 2023. Inspection by "S". Date of 09-15-2023.

For obsolete labelling / packaging it was confirmed that facility had a mill where they destroy and compact all the packaging. Evidence that further supplier of packaging is controlled reviewed in 4.12.

5.6 Product inspection, on-site product testing and laboratory analysis

It was confirmed that facility manage products that are not high care or high risk. According to the HACCP evaluation, they stablished an inspection product testing where they included the following program documented in platform. During audit it was followed the tests sensory, physical, chemical and microbiology of vertical audit and traceability exercise.
- Validation and Verification of shelflife: 1) Aptitude test on August 29th, 2023 / They consider variables: acidity. 2) Checklist for shelf life studies AC /vda/01 Date of 09-21-2023. Adobo chipotles. No deviations.

Pathogen testing is done according to program and according to the specification. Is not done to 100% the batches of finished products, is done according to the program and done by external supplier (not done in the facility, no risk of contamination observed during audit.

Facility did not have any laboratory. Facility performed analysis for releasing finished products with external supplier:
- Heavy metals. Lead, Cadmium, 04-21-2023.Anaysis with external lab “A”. No deviations.

- Microbiology. Analysis of 04-21-2023. External supplier "E". Aerobic mesophiles, fungi, yeasts, total coliforms, E coli, Lactic acid. No deviations.
- Pesticides. External lab “A” Analysis, Date of 10-23-2023. No deviations.

During audit it was interviewed quality staff, they answered correctly regarding their techniques for releasing products. They had available their procedures. Staff interviewed had a bachelor’s degree. For assuring they have reliable and confident results they performed analysis:

- Chile. ACIT/TRI / Records of February 14th, 2025. Defectives: ACMPREV. Critical characteristics: rotten, fungus, dehydrated.
- Packaging reception. Can: Weight, size, zest

Procedures reviewed:

- AC-PRO-IEQ procedure packaging reception procedure.
- Military standard AC-ME-Sampling.
- Certificate MF01P 26 02 F02.

5.7 Product release

For product release facility stablished that they must follow the next steps: Formulation liberation: The most critical part of the process it was confirmed that is the formulation area. In mixing area all products are evaluated before the packaging area.
During site inspection it was followed up the correct formulation of the product and confirmed that all ingredients were added according to specification. Analysis in this area is done by quality technician.
Analysis followed:

- Critical defects: rotten, rotten, fungus, yellow, dehydrated, seed.
- PGR-MP-01 Certificate / Date of October 2, 2023.

5.8 Pet food and animal feed

5.8 It was confirmed that facility do not produce pet food products

5.9 Animal primary conversion

5.8 No animal primary conversion done on facility

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
5.2.3	No label responsibilities from clients since all products are from site.
5.2.4	Not cooking instructions
5.4.5	Confirmed that there are no claims oversaw by the facility.
5.4.6	Confirmed that there are no claims oversaw by the facility
5.4.7	Confirmed that there are no claims managed by the facility
5.8	It was confirmed that facility do not produce pet food products
5.9	No animal primary conversion done on facility

6. Process control

6.1 Control of operations

During site inspection and traceability challenge during audit it was reviewed the process controls of the facility. The process did not have any CPP, but they had the following controls, for facility they identified that they are their quality parameters. During site inspection it was followed up the correct formulation of the product and confirmed that all ingredients were added according to specification. Analysis in this area is done by quality technician. Analysis followed:

- Observation reviewed of defects detected: rotten, rotten, fungus, yellow, dehydrated, seed.
- Quantity review: Records of 2023 with no deviations
- Weight review: Records 2023 with no deviations.

Once preparation is liberated by quality team, then the next verification is done by production and quality team regarding legal and quality issues. Evidence reviewed from the vertical audit and traceability exercise with no deviations.

Rework is not done of facility. If they have non-conform product confirmed that they must pass product again to the optical selection device.

Interviews were done for key staff of controlling the process such as: feeders, Production responsible, operators, Quality specialist. It was confirmed that they stablished that critical equipment were only controlled.
Process in-line monitoring devices for quality, they are the reviewed for food safety.

- RH-CA-LA-1 / Date of October 30, 2023 / Fundamentals of crimping (microbiological recontamination, definitions, overlap).
- ACPT/ 11. 3-10-2023. Physicochemical parameters, quality defects, sensory characteristics, evaluation of primary packaging, coding and labeling. Liberation. Release without deviation.

6.1.7 No products / materials out of the scope of the audit detected during site inspection

6.2 Labelling and pack control

During site inspection it was confirmed that the facility performed production of products that are packaged in a bulk and in sacks. Packaging material is inspected at the arrival to the facility. Evidence reviewed:

- Inspection records from quality staff of 2023. No deviation observed.

During site inspection, it witnessed production of the product of the scope. It was confirmed that there was no other packaging rather than the one that is produced.

During audit it was audited the clearance process, it was observed that before production, it was confirmed that facility performed cleaning inspection and during this they confirmed that they have no other product that the one that is produced AC-PRO-IEQ.

Commencing the production was confirmed during site inspection that they verify labelling and packaging materials and reported in their Production records. No deviation observed.

- Record Date November 2023. Reception label Measurements, weight, lithograph review. Data sheet.

6.2.4 no online verification equipment

6.3 Quantity, weight, volume and number control

It was confirmed that facility filled their products in a filling machine. It was observed how they at the beginning, at the end and during the release of the product they performs verification of weight. It was confirmed that they didn't have any deviation regarding legal requirements of weight. Also, it was reviewed during traceability challenge weight control of the product.

- The quality department analyzes 7 monitoring per batch (546 boxes). Average is done every 3 pallets.
- F-PEM-01-35 Modification in production line and spectim / rank person / Quality / Operator / Date of 12-15-2023.
- Weight calibration tests / 12-15-2023 / weight tests after modifications.

During audit it was followed up the scales used for weight verification, they are calibrated annually according to the program. Evidence reviewed in 6.4.

6.4 Calibration and control of measuring and monitoring devices

During audit it was confirmed that facility had identified that the instruments that must calibrate. It was confirmed that they are listed on procedure for maintenance, verification, calibration of Calibration plan 2023: AC-CAL-EQM scale inventory and Listing Laboratory equipment, it included:

- Area, location, equipment, brand, model, series.
- Procedure calibration and control of measurement and monitoring devices.

During site inspection it was confirmed that these instruments were properly identified and protected from damage. Also, it was interviewed operator staff, and all answered that the only person authorized for use them was Quality manager. When these instruments were calibrated, there was not the need for adjusting them, but they stablished that in case of deviation they must follow the last product elaborated in the site. No deviation observed. During audit it was followed up the following calibration, all were done by external supplier accredited 17025 and used traceable patterns. Evidence reviewed:

- Semi-annual: Calibration certificate. Liquid thermometer. Date of January 28, 2024. Calibration range is made from 25, 51, 69 and 90. Calibration. January 28th, 2023."MC" calibration. Accreditation. PJLA 71793.
- Metal detector calibration: Date of January 6th, 2024. External supplier "D". Accreditation PJLA 101514. Ferrous 2.5, Non-ferrous 3.5, and Stainless 5.
- Pontentiometer / Calibration Date of January 14, 2024. / Solutions: 4, 7, 10. No deviations.
- Videosim / Cali ration December 11th, 2023.
- Magnets: Date of. January 6, 2024/ Magnetic plate. 1567 Gaus / 1800 GAUS minimum 70%.
- Calibration of the A10 Scale: Date of January 14, 2023. External supplier "C".

Confirmed that accreditation was reviewed of the laboratories of 17025 of external suppliers.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.1.7	No products / materials out of the scope of the audit detected during site inspection.
6.2.4	No online verification equipment

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

It was confirmed that facility stablished that all staff before entering working to the facility they must receive training. During audit it was followed the training done to fresh staff:

- Onboarding: Induction: "JM" Induction topics: GMP, HACCP, allergens, policy, and BRCGS topics. It was confirmed that Production Managers were aware and with constant supervision for the production staff.

For production staff, it was interviewed production staff and it was confirmed that they were trained correctly and with awareness regarding quality, food safety, authenticity, and legality. It was confirmed that facility had a documented training produce and a Training program where they identified all the required training to be delivered to staff during al the year. During audit it was followed up the following trainings:

- HACCP Training Date: 01-21-2023.
- BRCGS v9 Date February 2023. Supplier: ATP from BRCGS.

It was confirmed that it was delivered training awareness course of Allergen. During this course it was delivered packing and labelling training.

- Training plan RHCA / GMP, Process control (labelling, 5S, Maher, kitchen, 6/10, barrels, machinist, pressure washing, crimping, thermal process, solid ratio, covering liquid.
- Training GMP: RH-CA-LA1 / Trainer "EH". Date of October 2nd, 2023.
- GMP, Color coding, Cleaning program, common areas. According to program RHCA/3. Evidence reviewed: November 17th, 2023. / Trainer "IO", "TA".

It was confirmed that attendance lists reviewed included name of the trainee, date and duration, title. It was confirmed that it was done in their language: Spanish. For confirming competency review, manager performs annual evaluation to staff. In case they need to improve in some respects, it was confirmed that topics were included in Training program.

- CPP: RH-CA-LA-1 / Date of October 30, 2023 / Fundamentals of crimping (microbiological recontamination, definitions, overlap).
- Training of labeling: RH-CA-LA1 / Date of 12-14-2023 / Training "CC".
- Followed training to external suppliers that work in the facility:
- Good practices, Order and cleanliness, Good storage practices. Training date: September 2023.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

It was confirmed that facility had a GMP procedure Manual of Good Manufacturing Practices Personnel appearance procedure where they stablished that all staff and visitors must followed them. Some of the rules they stablished: access without jewellery, use of shoes, clean uniform, access without perfume, use of cap, hand washing, hand disinfection, shoe sanitization. This practice was confirmed that were followed during site inspection and it was reviewed record of GMP verification (Evidence reviewed in 3.4. 4). It was confirmed that prior entering to production areas, there an area where staff can wash their hands, they have some instructions where staff can review correct hands washing.

During site inspection it was challenged production operators, reviewing them the stat of their hands, and no ills were observed. It was confirmed that in case of cuts and grazed, Production manager will evaluate the condition of the staff and if there is a risk of contamination staff must not enter to the sensitive areas. It was confirmed that facility had the Wound Management Procedure RH-BPM-BS. The injured staff is transferred. Band-Aids were used with metal detector bandages. Facility challenged metal detector with every batch of the metal detector bandage.

- Record reviewed: ACFS/2. Date: January 8th, 2023. Batch A16522.

During site inspection it was interviewed production staff and answered that they are not allowed to have personal medicines, they only be consumed, if necessary, in dedicated places. It was confirmed that there was no evidence of medicines in production/warehouses areas. All medicines that were observed controlled in a list:

- Record reviewed "Controlled Medicine Record 2024.

7.3 Medical screening

It was confirmed that according to the procedure SS-AC-EEI full time employees, when they were new in the facility, thew had medical screening (physical exploration, pharyngeal exudate, copro, febrile reactions, blood counts), screening done by an external clinical laboratory and evaluation by the doctor according to procedure: Evidence reviewed:

- Employee file: January 2024.
- Analysis of the external laboratory “C”. Copro, exudate, febrile reactions.

Reviewed an example of a deviated analysis of an employee.

- Area change request format / FSCA-01 / January 2024
- February 2024. Reanalysis by external supplier “SD”.

It was confirmed that facility had Attention to infectious diseases procedure RH-BPM-S. In case of deviation facility stablished relocating sick personnel from their duties to an area that does not compromise the safety of the product and is notified. According to Quality manager, it was stablished that in case that staff had any illness, staff must go to the doctor and once they are with the condition they can re-enter to the sensitive areas. All visitors, when entering the facility, they must answer a Health questionnaire. It was confirmed that in was stablished in the Security and hygiene measures to access to the facility. During site inspection it was not noticed sick staff. Medicines are not allowed they must be recorded with medical service.

7.4 Protective clothing: employees or visitors to production areas

It was confirmed that facility had protective clothing Manual RH-BPM-UNI where they stablished the use of uniforms. They did not use protective clothing. They stablished that all cloth is washed by internal laundry. During site inspection it was interviewed staff and they answered the following:

- Uniform used: Gown, apron, long shirt (maintenance). T-shirts.
- The uniform was washed at the facility
- They do not mix the work uniform.
- Do not mix with clothes that do not contain dirt
- Dry it indoors and protect it from rain.

During site inspection it was confirmed that production staff used uniform according to their areas they work. It was interviewed staff and they confirmed that they received sufficient uniforms. It was confirmed in site inspection that all uniforms were clean, with the absence of bottoms, and with no bags in the upper part.
During site inspection reviewed the laundry room, confirmed they used chemicals without odour.
It was confirmed that production operation in some point they use gloves, which are changed each production batch. Quality manager performs periodically inspection for assuring clothes were clean and in good conditions. Protective clothing that is not cleaned by the facility (cloth that is below uniform) is cleaned by themselves. Gloves policy reviewed, only nitrile material is allowed colour blue.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	

8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Equipment and maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

Module 11: Meat Supply Chain Assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	

11.3 Raw material receipt and inspection
Click or tap here to enter text.
11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
Click or tap here to enter text.
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
Click or tap here to enter text.
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
Click or tap here to enter text.
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)
Click or tap here to enter text.
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)
Click or tap here to enter text.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.